NATIONAL WOMEN'S HEALTH NETWORK

August 29, 2000

TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

5599 '00 SEP -5 A11:16

FROM: Amy Allina, Program and Policy Director

RE: Comments on Draft Guidance for Industry: Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients [Docket No. 00D-1350]

On behalf of the National Women's Health Network, a consumer advocacy organization devoted to women and health, I am pleased to submit these comments about the FDA's draft guidance for industry titled "Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients."

We would first like to express our support for some of the proposed changes to the labeling guidance. We are especially pleased to see the expanded language in the Precautions section about sexually transmitted diseases (STDs). The overall simplification of language is also an important improvement.

Our greatest concern lies with the patient labeling section. The omission of any information about warnings, precautions and side effects is completely unacceptable. Women cannot rely on physicians to communicate this essential health information to them. And even those women who do receive such information from their health care providers must also be given information that has been designed for the consumer to take home with their pills. The patient label should include specific information about the following topics:

- effectiveness of oral contraceptives
- contraindications to oral contraceptive use
- risks of taking oral contraceptives
- warning signs that a health problem associated with oral contraceptive use might be developing
- side effects of oral contraceptives
- precautions, including information about the lack of protection against STDs

We have been informed that the agency is aware that the current draft guidance is incomplete and that it intends to issue a separate guidance regarding the Patient Package Insert. We look forward to reviewing that draft and providing comments on it, however, in the interim we are registering our concern and stating our belief that it is critical that the agency not release this guidance in this incomplete and misleading form.

Thank you for the opportunity to comment on this draft guidance. If you have any questions about the Network's comments, I would be happy to discuss them.

Founders • Barbara Seaman • Phyllis Chesler, Ph.D. • Belita Cowan • Alice Wolfson • Mary Howell, M.D.

The only national public-interest membership organization devoted solely to women and health
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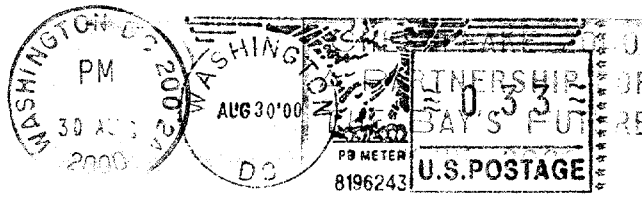

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